AUG 2 5 2005

SENTINEL
DIAGNOSTICS

510k Summary
Sentinel Iron Liquid

K Number: K051115

1. Submitter's information:

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2. Contact person:

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3. Date summary prepared: 21 August 2005

4. Device name and classification

The Sentinel Iron Liquid described in this 510(k) consists of reagents and standard, packaged and distributed in one kit. The device is intended to be sold as an *in-vitro* test for professional use.

Product name and classification information are provided in Table 4.1 below.

Table 4.1 Device names and classification of Iron Liquid

Trade/Device Name	Regulation Number	Regulation name	Classification panel	Regulatory class	Product Code
Iron Liquid	21 CFR 862.1410	Direct Colorimetric, Iron	Clinical Chemistry	I	CFM

5. Device description

The Iron Liquid described in this 510(k) submission is composed of reagents and standard, packaged and distributed in the same kit. The device is intended to be sold as an in vitro test for professional use.

The Iron Liquid is a direct colorimetric in vitro diagnostic assay for the quantitative determination of iron without deproteinization in human serum and plasma (heparin salt, only). In a pH 4.0 buffer system, iron is released from transferin to which it is bound, and then quantitatively reduced to a ferrous state. The iron forms with Ferene-S a stable colored complex of which the color intensity is proportional to the amount of iron in the sample. Particular reaction conditions and a specific masking agent eliminate the interference from copper.

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6. Intended Use

The Sentinel Iron Liquid is a direct colorimetric in vitro diagnostic assay for the quantitative determination of Iron without deproteinization in human serum and plasma (heparin salts, only).

Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease, CFR 862.1410

7. Comparison with Predicate Devices

Table 7.1 lists the predicate device for the Sentinel product included in this submission, and provides information on the regulatory status of the predicate device, including the 510(k) number.

Table 7.1 Predicate device for Sentinel UIBC Liquid Diagnostic Assay

Sentinel Trade Device Name	Predicate Device Name	Predicate Device Manufacturer	Predicate device (k)	FDA clearance date
Iron Liquid	IL Test Iron	Instrumentation Laboratory Company	K972363	15 Aug 1997

Table 7.2 below report a comparison of the Sentinel UIBC Liquid with the Predicate Device Roche UIBC. No substantial differences can be noted. The two devices are intended to be used on Automatic Analyzers: the predicate device with the Roche/Hitachi analyzers, the Sentinel UIBC Liquid on the Abbott AEROSET and ARCHITECT analyzers.

Table 7.2 Comparison with Predicate Device

#	Design Feature	New Device Iron Liquid	Predicate Device IL Test Iron
1	Sample Type	Human serum and plasma (only heparin salts)	Same
2	Technology	Direct colorimetric without deproteinization	End Point, Colorimetric
3	Manufacturer	Sentinel	Same
4	Instrumentation	Abbott AEROSET and Abbott ARCHITECT *c*8000 analyzers	IL Lab 600/900/1800 Plus Chemistry System

8. Performance Data

Performance evaluations included sensitivity, intra- and inter-assay precision and method comparison.

9. Conclusion

The performance and safety data presented in this premarket notification support a finding of substantial equivalence between the Sentinel Iron Liquid and the predicate devices specified in this submission.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2005

Mr. Davide Spada
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Italy

Re: k051115
Trade/Device Name: Sentinel Iron Liquid
Regulation Number: 21 CFR 862.1410
Regulation Name: Iron (non-heme) test system
Regulatory Class: Class I, reserved
Product Code: JIY
Dated: July 13, 2005
Received: August 8, 2005

Dear Mr. Spada:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051115

Device Name: Sentinel Iron Liquid

Indications For Use:

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Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051115